UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	
	)	**Case No. 1:17-MD-2804**
THIS DOCUMENT RELATES TO:	)	
	)	**Judge Dan Aaron Polster**
Track Three Cases	)	
	)	**OPINION AND ORDER GRANTING IN PART PHARMACY DEFENDANTS' MOTION TO EXCLUDE TESTIMONY OF ANNA LEMBKE**

Before the Court is the Pharmacy Defendants' Motion to Exclude Anna Lembke. Plaintiffs filed an opposition brief and Defendants filed a reply brief. The Court also held a *Daubert* hearing on September 10, 2021, where the Court and counsel questioned Lembke regarding the scope of her opinions, qualifications, and expertise. Upon careful consideration of the parties' briefs and arguments and the supporting evidence, for the reasons set forth below, the Motion is **GRANTED IN PART AND DENIED IN PART**.

Lembke is a medical doctor with expertise in pain medicine and addiction. She seeks to offer opinions about a range of topics, including addiction, the history of opioid marketing and prescribing, and Defendants' role in the opioid epidemic, including their dispensing practices. As part of these opinions, Lembke concludes Defendants ignored "red flags" for the misuse and diversion of opioids and failed to analyze their own dispensing data to assist individual pharmacies in identifying such "red flags."

Defendants assert Lembke lacks the necessary qualifications to testify as an expert on pharmacies' opioid policies and dispensing practices. They also argue Lembke's opinions are unreliable and would mislead a jury. The Court agrees that Lembke is not qualified to testify about

certain aspects of the pharmacies' operations and policies. Accordingly, as explained in Section IV(a)(1) below, the Court will exclude certain portions of her opinions on those topics. As to Lembke's remaining opinions, the Court finds Defendants' challenges are unfounded.

I. Legal Standard

The Court hereby incorporates the legal standard set forth in the Court's Opinion and Order regarding *Track One-A* Defendants' motion to exclude the opinion and testimony of Prof. Meredith Rosenthal. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934597, at *1–*5 (N.D. Ohio Aug. 20, 2019) (Doc. #: 2495 at 1–10).

II. Credentials and Experience

Lembke received a medical degree from Stanford University School of Medicine in 1995, and also completed there a partial residency in pathology (1997), a full residency in psychology (2000), and a fellowship in mood disorders (2002). Lembke Rpt. (Doc. 3852-8 at 1). From 2001 to the present, she has taught medical students, residents, and fellows at Stanford University School of Medicine on a variety of topics related to psychiatry, addiction, and pain. *Id.* Lembke sits on numerous medical boards and committees, such as the California Society of Addiction Medicine and the Addiction Medicine Fellowship Director Association. *Id.* at 2. She is also the author of a book on the prescription drug epidemic: *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* (Johns Hopkins University Press, 2016). *Id.* at 3. Ultimately, her expertise is based on her three related roles as clinician, researcher, and teacher.

III. Opinions

Lembke offers the following opinions:

1) The addictive nature of medicinal opioids has been known for centuries. The Pharmaceutical Opioid Industry's misrepresentations of the safety and efficacy of prescription opioids reversed a century of appropriate restrictions on the use of these dangerous drugs, and substantially contributed to the current opioid epidemic;

2) Addiction is a chronic, relapsing and remitting disease with a behavioral component, characterized by neuroadaptive brain changes resulting from exposure to addictive drugs. Every human being has the potential to become addicted. Some are more vulnerable than others. Risks for becoming addicted include genetic, developmental, and environmental factors (nature, nurture, and neighborhood). One of the biggest risk factors for addiction is simple access to addictive drugs. When supply of an addictive drug is increased, more people become addicted to and suffer the harms of that drug. Prescription opioids are as addictive as heroin, and the Defendants' conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction and overdose death;

3) Opioid prescribing began to increase in the 1980s and became prolific in the 1990s and the early part of the 21st century, representing a radical paradigm shift in the treatment of pain and creating more access to opioids across the United States;

4) The Pharmaceutical Opioid Industry contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids. The Industry disseminated these misleading messages through an aggressive sales force, key opinion leaders, medical school curricula, continuing medical education courses, clinical decision support tools, professional medical societies, patient advocacy groups, the Federation of State Medical Boards, and The Joint Commission;

5) Opioid distributors collaborated with opioid manufacturers and pharmacies to promote sales of opioid pain pills. Such coordinated efforts included programs to give away free samples of opioids, coupons to discount opioids, and promotion of specific opioid products under the guise of education. These activities increased the population of opioid users, dose and duration of opioid use, and the risk of opioid misuse, addiction, dependence, and death;

6) Pharmacies leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community. They alone had direct contact with opioid manufacturers and distributors upstream, and patients and prescribers downstream. Their coordinated efforts to "create demand" included advertising specific opioid products at the pharmacy counter, building opioid "Super Stores" to enhance unrestricted flow of opioid pain pills, spreading misinformation about the safety and efficacy of opioid pain pills,

partnering with pro-opioid industry advocacy and lobbying organizations, ignoring "red flags" for misuse and diversion including concerns expressed by their own pharmacists, failing to provide pharmacists with sufficient time, resources, or incentives to investigate red flags, and failing to use or analyze their own dispensing data to assist pharmacies in identifying red flags. By increasing and assuring the supply of opioids and failing to provide effective controls against diversion, pharmacies contributed to opioid misuse, addiction, dependence, and death;

7) No reliable scientific evidence shows that long-term opioid therapy is effective for chronic non-cancer pain;

8) The Pharmaceutical Opioid Industry misrepresented that the risk of addiction to prescription opioids is "rare," or "less than 1%," when in fact prescription opioids are as addictive as heroin, and the risk of addiction is far higher than stated by the Industry. The best, conservative data show an opioid addiction prevalence of 10–30% among chronic pain patients prescribed opioids;

9) Increased supply of prescription opioids contributed substantially to more individuals becoming addicted to opioids and transitioning from prescription opioids to illicit sources of opioids such as heroin and fentanyl (The Gateway Effect);

10) Increased supply of prescription opioids contributed substantially to more individuals, including newborns, becoming dependent on opioids, increasing their risk for opioid-related morbidity and mortality (The Dependence Effect);

11) Increased supply of prescription opioids contributed substantially to diversion of prescription opioids to individuals for whom they had not been prescribed (The Tsunami Effect);

12) The increased supply of prescription opioids through licit and illicit sources resulted in a prescription opioid epidemic in the United States. "Epidemic," defined as an outbreak of disease that spreads quickly and affects many individuals at the same time, is the appropriate term to describe the increase in opioid related morbidity and mortality beginning in the 1990s and continuing to the present day;

13) There is no doubt a cause-and-effect relationship exists between the oversupply of prescription opioids and the opioid epidemic;

14) For the reasons explained, the Pharmaceutical Opioid Industry bears responsibility for the misrepresentation of safety and efficacy, the ubiquitous distribution of prescription opioids, and the unchecked dispensing of prescription opioids, which resulted in the ongoing epidemic. To the extent that other factors contributed, those conditions were exploited by the Industry to increase the extent of harm; and

15) Ending the epidemic of opioid addiction, dependence, and death will require significant investment of resources. An effective strategy will be multifaceted and

> will accomplish the following: prevent new cases of addiction, dependence, and death (primary prevention), limit progression of harm (secondary prevention), and treat existing cases (treatment). These changes will require curbing opioid prescribing, re-educating patients and health care providers, creating de-prescribing clinics, promoting naloxone and other harm-reduction strategies, and building an enduring medical infrastructure to treat addiction.

Id. at 7–9.

IV. Analysis

Defendants ask the Court to exclude most or all of Lembke's testimony because: (1) she is not qualified to opine about pharmaceutical marketing; (2) her methodology is unreliable, as it focuses on national data and not the activities or policies of Defendants in Lake and Trumbull Counties; (3) her opinions regarding whether prescriptions had a "legitimate medical purpose" are unreliable and rest on a flawed understanding of that term; (4) her use of the phrase "pharmaceutical opioid industry" is misleading; and (5) she is not qualified to opine on the practice of pharmacy or dispensing practices.[1] *See* Motion at 1–2, 8; Reply at 1–2. The Court addresses each argument below.

Marketing Causation

Plaintiffs ask the Court to revisit its *Track One* order limiting Lembke's testimony and find now that she is "qualified to opine on the cause-and-effect relationship between false and misleading promotion, increased opioid prescribing, and increased harms." Response at 15–16. In *Track One*, the Court ruled that Lembke "is 'fully qualified' to opine on matters involving

[1] Without elaboration or argument, Defendants in their moving brief also ask the Court to continue to exclude Lembke's marketing causation opinions the Court excluded in its *Track One* order. In their Opposition, Plaintiffs ask the court to reconsider that order and allow Lembke to testify on marketing causation, and Defendants respond to this request in their Reply. Although Plaintiffs' request ought, perhaps, to have been the subject of a separate motion, the Court addresses it below.

medical facts and science that falls within these areas." *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4054998, at *6 (N.D. Ohio Aug. 28, 2019) (Doc. 2549 at 11). The Court further permitted Lembke to testify about various aspects of the opioid manufacturers' marketing efforts, and "how doctors, in general, rely on such information in making prescribing decisions." *In re Opiate*, 2019 WL 4054998, at *6, (Doc. #: 2549 at 12-13). But the Court ruled ***narrowly*** that she was not qualified to offer her opinion and testimony "regarding a ***causal connection*** with respect to pharmaceutical marketing, *i.e.* that Defendants' marketing efforts resulted in increased sales and/or increased supply of prescription opioids." *In re Opiate*, 2019 WL 4054998, at *6, (Doc. #: 2549 at 12) (emphasis added).

Plaintiffs assert "substantial new or additional evidence" not introduced in *Track One* indicates that Lembke has expanded her field of expertise in the intervening years. For example, Lembke has since "given presentations 'to doctors, legislators, and the public' on 'the causes of the opioid epidemic[,]'" a "significant portion" of which involved "describing the false and misleading messages promoted by the Pharmaceutical Opioid Industry as detailed in this Report." *Id.* at 16 (quoting Lembke Rept. at 5. Additionally, courts in California and New York have found Lembke qualified to testify on the effects of the opioid industry's promotion of opioids. Response at 17–19.

The Court has reviewed the "new or additional evidence" of Lembke's recent activities and is not persuaded that it provides cause to revisit the prior ruling limiting her testimony. The only explicit reference to a new activity that post-dates the Court's *Track One* order indicates she gave a lecture at Duke University in 2020 on the subject of "market-driven epidemics." Response at 17, Lembke Rept. at 6. Although the Background and Qualification section of Lembke's *Track Three* report contains a new paragraph detailing her teaching on the marketing of opioids and the

"impacts of such marketing on the prescribing habits of physicians," *id.*, the Court is not persuaded that this new narrative account of her two decades of teaching supports any change to the Court's prior ruling, notwithstanding the differing views taken by the courts in New York and California. At the time of its *Track One* ruling on Lembke, the Court was aware of her expertise in opioid marketing, which is why it allowed her to testify, within limits, on that subject. *In re Opiate*, 2019 WL 4054998, at *6 (Doc. #: 2549 at 11–13). The Court will not alter its prior ruling.

Methodology

Defendants argue Lembke's methodology is unreliable because her analysis is national in scope and did not examine Defendants' dispensing and pharmacy operations specifically in Lake and Trumbull Counties. Motion at 6–7; Reply at 5–6. Plaintiffs contend national data can be used to create a reasonable basis for an inference about the conditions in Lake and Trumbull Counties, unless the situation in those counties is shown to significantly differ from the national data. Response at 10–11.

The Court agrees with Plaintiffs. National data and practices may be used to demonstrate local conditions where it is reasonable to assume that the national and local environments are similar. *See In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 44 (1st Cir. 2013); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 4011729, at *2–3 (Doc. #: 2542 at 3–5) (allowing expert opinion based on national data in absence of data specific to bellwether counties). Defendants do not argue the pharmacies' roles in the opioid epidemic manifest differently in Lake and Trumbull Counties, as compared to the rest of the country, in any material way. In fact, Defendants highlight testimony from Lembke stating she has no reason to believe the pharmacies in Lake and Trumbull

counties differed materially from national trends.[2] Absent such a showing of material difference, the national rather than regional character of the data speaks to the evidence's weight, not its admissibility.

Accordingly, the Court declines to exclude Lembke's testimony on the ground that it is unreliable.

The Legitimate Medical Purpose Requirement

Defendants contend any testimony from Lembke stating whether prescriptions were dispensed for a "legitimate medical purpose" should be excluded as unreliable. Specifically, Defendants point to deposition testimony in which Lembke states she believes most doctors thought they were prescribing opioids for a legitimate medical purpose, though she argues the doctors did so because they were "duped" into overprescribing by marketing campaigns designed to mislead them. Motion at 9–10. Defendants argue Lembke admits that, because doctors believed in good faith there was a legitimate medical purpose for prescribing opioids, the pharmacists filling those prescriptions necessarily complied with their "corresponding responsibility" under the Controlled Substances Act ("CSA") and applicable regulations to ensure the prescriptions were written for legitimate medical purposes. *Id.* Plaintiffs respond that determining whether a pharmacist has met their corresponding responsibility is not a subjective inquiry into the

[2] Specifically, Lembke stated, "I think that what was happening nationally was also happening in Lake and Trumbull County. I don't have any data to the contrary, but I can't identify a specific pharmacist by name in Lake or Trumbull County[,]" and "I have no reason to believe the pharmacies in Lake and Trumbull County are exempt from that, including pharmacies that are not named in this case." Lembke Dep. Tr. at 7.

prescriber's state of mind, but rather rests on objective indicia, such as the presence of red flags of diversion and whether the pharmacist has investigated and resolved them. Response at 13–14.

The Court does not accept Defendants' subjective approach to the pharmacist's corresponding responsibility. Under the applicable regulations, a doctor and a pharmacist have ***independent*** duties to analyze prescriptions for controlled substances, to determine if they have a legitimate medical purpose. *See* 21 C.F.R. § 1306.04(a). While the Court agrees with Defendants that this analysis must be carried out in good faith, it also must be based on objective factors (*i.e.*, red flags). *See, e.g.*, *Jones Total Health Care Pharm., LLC v. DEA*, 881 F.3d 823, 830 (11th Cir. 2018) (*per curiam*) (sustaining revocation of pharmacy's CSA registration, concluding the evidence of more than 100 prescriptions filled with unresolved and unresolvable objective red flags "support[ed] the agency's determination that Jones Pharmacy unlawfully filled numerous controlled substance prescriptions that were not issued for a legitimate medical purpose"). Indeed, it is hard to imagine how any such analysis that does not examine objective factors could truly be in good faith. Plaintiffs argue that a standard that only looks at the prescribers' subjective state of mind could lead to absurd results, such as determining "that a pharmacist who dispenses opioids to a known doctor-shopping patient fulfills her corresponding responsibility as long as the doctor-shopper has successfully deceived the prescribing doctor." Response at 14. The Court agrees. Even if a doctor prescribes opioids in good faith to "Patient X," with no knowledge of any red flags, a pharmacist who knows Patient X has attempted to fill two *other* opioid prescriptions from *other* doctors during the same week would surely fail to discharge her corresponding responsibility by simply filling all of those prescriptions. The Court rejects the subjective standard Defendants suggest. Moreover, Defendants offer no legal authority demonstrating a subjective inquiry is the correct one.

Accordingly, the Court declines to exclude any testimony by Lembke discussing whether prescriptions were issued for a legitimate medical purpose.

The "Pharmaceutical Opioid Industry"

Defendants argue that, even if the Court allows Lembke to testify, it should preemptively prohibit her from using the phrase "Pharmaceutical Opioid Industry" to attribute actions of opioid manufacturers to pharmacies. In response, Plaintiffs highlight several different marketing efforts undertaken collaboratively by pharmacies and other actors, including manufacturers, which Plaintiffs claim jointly contributed to the opioid epidemic. In view of these joint marketing initiatives, Plaintiffs maintain any determination of whether specific testimony incorporating the phrase "Pharmaceutical Opioid Industry" is misleading is best handled at trial. Response at 12.

The Court agrees with Plaintiffs only to the extent that it will not now issue a broad, preemptive ruling. Defendants are correct it would be inappropriate for any witness to use the phrase "Pharmaceutical Opioid Industry" (or similar wording) to attribute to the Pharmacy Defendants actions committed only by opioid manufacturers, for example. On the other hand, there may be instances where reference to the "Pharmaceutical Opioid Industry" is not inappropriate. *See Keyes Daubert Opinion*, Doc. #: 3946 at 8 n.6 (directing that parties and witnesses should not use terms that "lump all of the Defendants together," but declining to exclude specific terms).

Determination of this question is best made in context at trial. Plaintiffs have already conceded that Lembke would have to connect any testimony at trial that does not apply to the opioid industry generally to the conduct of specific Defendants. Response at 12–13.

Pharmacy Practices and Policies

Defendants assert Lembke is not qualified to testify as an expert on the policies and practices of pharmacies, or a pharmacist's standard of care, because she has no education or direct experience within the field of pharmacy. Motion at 4–6; Reply at 2–5. Plaintiffs respond that Lembke's knowledge and experience as an addiction expert and medical doctor, who works closely and collaboratively with pharmacists, qualify her to opine on pharmacies' policies and dispensing practices. Response at 3–10. Lembke also notes she has reviewed numerous documents produced in discovery related to education received by pharmacists regarding opioid use, including courses provided or underwritten by Defendants.

Lembke's report spans 478 pages (including exhibits) and, as she summarizes them above, comprises 15 distinct opinions. Defendants do not cite specifically to any language in Lembke's Report (as opposed to a few excerpts from her deposition) on the topic of pharmacy policies and practices that they seek to exclude. In their response, however, Plaintiffs assume Defendants are referring to segments of her sixth opinion, repeated here:

> Pharmacies leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community. They alone had direct contact with opioid manufacturers and distributors upstream, and patients and prescribers downstream. Their coordinated efforts to "create demand" included [1] advertising specific opioid products at the pharmacy counter, [2] building opioid "Super Stores" to enhance unrestricted flow of opioid pain pills, [3] spreading misinformation about the safety and efficacy of opioid pain pills, [4] partnering with pro-opioid industry advocacy and lobbying organizations, [5] ***ignoring "red flags" for misuse and diversion including concerns expressed by their own pharmacists,*** [6] ***failing to provide pharmacists with sufficient time, resources, or incentives to investigate red flags, and*** [7] ***failing to use or analyze their own dispensing data to assist pharmacies in identifying red flags.*** By increasing and assuring the supply of opioids and failing to provide effective controls against diversion, pharmacies contributed to opioid misuse, addiction, dependence, and death;

Lembke Rpt. at 8 (emphasis added). The language emphasized above in bold falls under the rubric of pharmacy policies and practices and a pharmacist's standard of care.

The Court finds Lembke has the expertise necessary to testify ***to some extent*** regarding these topics. The record demonstrates Lembke is highly distinguished as a medical expert in the scientific disciplines of psychiatry, addiction, and pain. Additionally, Lembke has experience with thousands of interactions with pharmacies and pharmacists in a professional capacity, particularly in the context of prescribing controlled substances such as opioids. Response at 5. These interactions require Lembke to engage with the practical, "in-the-store" effects of pharmacies' dispensing policies and practices on a daily basis. Moreover, Lembke's expertise in the epidemic of opioid addiction qualifies her to opine generally on the downstream effects of the actions the pharmacies took or did not take in carrying out their business.

Defendants would require that an individual possess a doctorate in pharmacy before they are qualified to offer ***any*** testimony regarding pharmacies. The Court disagrees. What is required instead is expertise in the factors that have fueled the opioid epidemic, such as the circumstances surrounding the supply and availability of opioids, as well as those related to the drug-seeking behaviors of opioid-seeking pharmacy customers (*i.e.* red flags). *See In re Welding Fume Products Liab. Litig.*, 2005 WL 1868046, at *5 (N.D. Ohio Aug. 8, 2005) ("An expert may be highly qualified to respond to certain questions and to offer certain opinions, but insufficiently qualified to respond to other, related questions, or to opine about other areas of knowledge."). The Court finds Lembke generally has such expertise.

Dr. Lembke's review of discovery produced in this MDL regarding the Pharmacy Defendants' policies and procedures is refracted through the lens of an expert in opioid medication, addiction, and treatment – she is certainly not simply a "lay person who read [up]" on the subject.

United States v. Paul, 175 F.3d 906 (11th Cir. 1999).[3] Further, the role of pharmacies and pharmacists clearly overlap and intersects with her areas of expertise. As an obvious example, certain circumstances should raise identical "red-flags" to both a doctor and a pharmacist (*e.g.,* efforts by a patient to obtain or fill simultaneous prescriptions for an opioid, a muscle relaxant, and a benzodiazepine).[4] Thus, Dr. Lembke is well-qualified by experience to opine on the efficacy and effects of many of Defendants' policies and procedures, such as Defendants' alleged "***ignoring 'red flags' for misuse and diversion including concerns expressed by their own pharmacists***." Lembke Report at 8 (quoting clause [5] of her sixth opinion).

Defendants are correct, however, that Lembke's expertise does not allow her to opine on any and every Pharmacy policy or procedure. For example, Lembke also opines that Defendants "[6] ***fail[ed] to provide pharmacists with sufficient time, resources, or incentives to investigate red flags."*** *Id.* But nothing in Lembke's background provides her a basis upon which to assess whether a Pharmacy sufficiently incentivized its pharmacist-employees to investigate a "red-flag." Lembke may properly opine that pharmacists should examine prescriptions for "red flags," and that failing to do so leads to misuse and diversion, but it is outside of her area of expertise to assert that internal workplace rules applicable to pharmacists precluded a "red flag" examination.[5]

Although the Court concludes Defendants are correct that Lembke's opinions occasionally extend beyond her qualifications, the Court will not extend its analysis through the rest of her lengthy report. "[T]he Court has neither the time nor the inclination to sift through the [hundreds

[3] *See* Daubert Hrg. Transcript (doc. #: 3944) at 38-40 (Lembke's opinions are based on the combination of her clinical experience, educational research, and review of litigation documents and DEA policy, summarized by the Court as "clinical practice, research, and study for this case").
[4] *Id*. at 5, 14-15, 43-44.
[5] To put a finer point on it, Lembke may opine that she believes pharmacists should be "given sufficient time and infrastructure and tools to check the PDMP," and that pharmacies should provide their pharmacists with "access [to] their own databases to check red flags," but she may not opine whether pharmacies' policies were sufficient or appropriate. Daubert Hrg. Transcript (doc. #: 3944) at 47.

of] pages of Dr. [Lembke's] Expert Report in search of an offending provision." *Alcatel USA, Inc. v. Cisco Sys., Inc.*, No. 4:00cv199, 2002 WL 34357200, at *1 (E.D. Tex. May 7, 2002). Defendants may object at trial that a given opinion is beyond Lembke's expertise, but their motion for a pretrial ruling excluding her opinions is otherwise denied.

IT IS SO ORDERED.

/s/ Dan Aaron Polster September 17, 2021
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE